



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/273,217	03/19/1999	XIN-YUN HUANG	19603/1451(C	6809

7590                    08/27/2002

MICHAEL L GOLDMAN  
NIXON PEABODY LLP  
CLINTON SQUARE  
PO BOX 31051  
ROCHESTER, NY 14603-1051

[REDACTED] EXAMINER

BASI, NIRMAL SINGH

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 08/27/2002      *Ly*

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. 09/273,217	Applicant(s) XIN-YUN HUANG
Examiner Nirmal S. Basi	Art Unit 1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Jul 3, 2002.

2a)  This action is FINAL. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 1-4, 6-9, 19-22, and 24-27 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-4, 6-9, 19-22, and 24-27 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892) 4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948) 5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6)  Other: \_\_\_\_\_

Art Unit: 1646

### **DETAILED ACTION**

1. Amendment filed 4/9/02 (paper number 18) and 6/4/02 (paper number 22) have been entered.

Applicant has canceled claims 10-18, 28-35 and amended claims 1, 6, 19 and 20.

2. The request filed on 6/4/02 for a Continued Prosecution Application (CPA) under 37 CFR

5 1.53 (d) based on parent application No. 09/273,217 is accepted and a CPA has been established.

An action on the CPA follows.

3. The rejection of claims 1-4, 6-9, 20-22 and 24-27 under 35 U.S.C. 112, second paragraph are withdrawn in view of Applicants arguments and Amendments filed in paper number 18.

4. The rejection of claims 1-8 and 19-26 under 35 U.S.C. 102 (b) and (e) are withdrawn in view 10 of Applicants arguments and Amendments filed in paper number 18.

5. The rejection of claims 1-4, 7-9, 19-22 and 24-27 under 35 U.S.C. 103 are withdrawn in view of Applicants arguments and Amendments filed in paper number 18.

### **Claim Rejection, 35 U.S.C. 112**

15 6. Claims 1-4, 6-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because the method steps do not achieve the goal of identifying an ion channel blocker for an ion channel. An acceptable method claim must contain three sections: 1) a 20 preamble, 2) method steps that clearly define what is to be done in each step, and 3) a conclusion that

Art Unit: 1646

what was stated in the preamble was achieved. The method provides an external vestibule portion of an ion channel. It is not clear how the inhibition of ion channel activity is determined in the absence of the part of the molecule required for ion transport.

Claims 2-4 and 6-9 are rejected for being dependent on indefinite base claim and fail to resolve the

5 issues raised above.

#### **Claim Rejection, 35 U.S.C. 112**

7. Claims 1-4, 6-9, 19-22 and 24-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for identifying an ion channel blocker or screening for a drug for effectiveness as an ion channel blocker for an ion channel, the method described as in claim 19, where the ion channel is Kv1.2, does not reasonably provide enablement for methods for identifying an ion channel blocker or screening for a drug for effectiveness as an ion channel blocker where the ion channel is not Kv1.2. The, specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

15 The methods of instant invention require a functional ion channel. The ion channel blocker must bind to the external vestibule, block ion transport, and ion transport must be measured to determine if the blocker has the desired effect. Claims 1-3 and 6-9 do not contain the limitation of having the complete ion channel or that it even be contained in a cell. Further there is no method step that determines if the blockage of the ion channel is due to the blocker binding to the external 20 vestibule. The blocking of the ion channel could be due to some other interaction. Also the method

Art Unit: 1646

cannot be practiced without functional ion channel. Further the method requires the binding of a compound to the external vestibule, which is defined as portion of the ion channel located between the S5 transmembrane and pore forming region of the ion channel or between the pore forming region and the S6 transmembrane of the ion channel. Ion channels are different in structure and function. All ion channels do not have 6 transmembrane regions. All potassium channels do not have 6 transmembrane regions. The external vestibule of these channels does not have the same structure. The specification discloses the effect of antibodies on Kv1.2 channels contained in a cell, but the scope of the claims encompasses all ion channels. Further there is no limitation that the ion channel be contained in a cell or the ion channel is functional. The critical feature of the invention is that the a specific external vestibule located in the Kv1.2 ion channel can be modulated to inhibit ion transport through a cell membrane. The external vestibule of the Kv1.2 ion channel is not found in all ion channels or shown to act in the same manner if constructed into a fusion protein. While the person of ordinary skill in the art would, in light of the specification be able to identify ion channel blockers or screen for drugs effective as ion channel blockers by using the external vestibule of the kv1.2 ion channel in the method disclosed as “enabled” above, the scope of the claims, which encompass any external vestibule, any ion channel (functional and non functional), is simply not enabled by the disclosure. The disclosure does not teach how to make use all external vestibules commensurate in scope with the claims. Due to the large quantity of experimentation necessary to identify if the external vestibules of other ion channels function in a similar manner, what parts of the ion channel constitute the external vestibule, the lack of direction/guidance presented in the

Art Unit: 1646

specification regarding the use of other ion channels apart from Kv1.2, the unpredictability of the structure and function, and the breadth of the claim which fail to limit to specific types of ion channel, undue experimentation would be required of the skilled artisan to make or use the claimed invention in its full scope.

5

8. No claim is allowed.

#### **Advisory Information**

10 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

15 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

20 Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi  
Art Unit 1646  
August 26, 2002

25

*Michael D. Pak*  
**MICHAEL PAK**  
**PRIMARY EXAMINER**